SEALED

FILED *IN CAMERA* AND UNDER SEAL IN ACCORDANCE WITH 31 U.S.C. §3730(b)(2)

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

ORIGINAL

UNITED STATES OF AMERICA	§	
and	§	
THE STATES OF ARKANSAS,	§	
CALIFORNIA, COLORADO,	§	
CONNECTICUT, DELAWARE, FLORIDA,	§	
GEORGIA,HAWAII, ILLINOIS,	§	
INDIANA, LOUISIANA, MARYLAND,	§	
MASSACHUSETTS, MICHIGAN,	§	
MINNESOTA, MISSOURI, MONTANA,	§	
NEVADA,NEW HAMPSHIRE,	§	
NEW JERSEY,NEW MEXICO, NEW YORK,	§	**CIVIL ACTION NO.**
NORTH CAROLINA, OKLAHOMA,	§	**3-11-CV-0486-P**
RHODE ISLAND, TENNESSEE,	§	
TEXAS, VIRGINIA AND WISCONSIN	§	~~**FILED IN CAMERA AND**~~
And	§	**UNDER SEAL**
THE DISTRICT OF COLUMBIA,	§	
	§	
***Ex rel.* TRACY GARSTKA AND**	§	
KIMBERLIE FIGG	§	
	§	
Plaintiffs,	§	
	§	
v.	§	
	§	**JURY TRIAL DEMANDED**
MEDTRONIC, INC., d/b/a MEDTRONIC	§	
DIABETES, MEDTRONIC MINIMED,	§	
INC., d/b/a MEDTRONIC DIABETES,	§	
MINIMED DISTRIBUTION CORP., and	§	
CCS MEDICAL, INC.	§	
	§	
Defendants.	§	

AMENDED COMPLAINT UNDER THE *QUI TAM* PROVISIONS OF THE FALSE CLAIMS ACT AND SIMILAR STATE PROVISIONS

Plaintiffs and Relators Kimberlie Figg ("Ms. Figg") and Tracy Garstka ("Ms. Garstka") (collectively the "Relators") file this Complaint against Medtronic, Inc., d/b/a Medtronic Diabetes, Medtronic Minimed, Inc., d/b/a Medtronic Diabetes, MiniMed Distribution Corp. (Medtronic, Inc., d/b/a Medtronic Diabetes, Medtronic Minimed, Inc., d/b/a Medtronic Diabetes and MiniMed Distribution Corp. will hereinafter be referred to collectively as "Medtronic"), and CCS Medical, Inc. ("CCS")[1] on behalf of the United States of America, the District of Columbia and the States of Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia and Wisconsin (hereinafter, collectively, "the States").

INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America and on behalf of the States due to Defendants' frequent and repeated acts of directly soliciting Medicare beneficiaries to purchase Medtronic insulin pumps and fraudulently inducing, coercing and frightening them into seeking the replacement of their working insulin pumps and Defendants' acts of submitting or causing the submission of false claims to Medicare, Medicaid and other federally-funded health care programs for new and replacement insulin pumps that were sold as a result of such direct solicitation.

[1] Medtronic, Inc., d/b/a Medtronic Diabetes, Medtronic Minimed, Inc., d/b/a Medtronic Diabetes, MiniMed Distribution Corp., and CCS Medical, Inc. will hereinafter be referred to collectively as "Defendants."

2. These false claims have been caused through (1) Defendants directly soliciting and encouraging Medicare and Medicaid beneficiaries to purchase pumps in violation of federal law, (2) Defendants' repeated acts of illegally contacting Medicare and Medicaid beneficiaries after the warranty expires on their insulin pumps and soliciting such beneficiaries to elect to replace or upgrade their insulin pumps even though the beneficiaries' current pumps work properly and even though there is no medical necessity for replacing or upgrading the beneficiaries' working pumps, (3) Medtronic's failure to honor its warranty on certain insulin pumps sold to Medicare and Medicaid beneficiaries as required by federal law and applicable state law such as ARK. ADMIN. CODE § 016.05-905, and (4) providing certain kickbacks to physicians for prescribing Medtronic's pumps and to patients for using Medtronic's pumps.

3. Pursuant to the requirements of 31 U.S.C. §3730(b)(2), this Complaint is filed in camera and under seal.

4. As evidenced by Defendants' own documents, these acts have resulted in false claims being presented to federal health care programs.

PARTIES

5. The United States of America and the States are the Plaintiffs on whose behalf the Relators bring this action pursuant to the False Claims Act, 31 U.S.C. § 3730 *et seq.*, and similar provisions of the laws of each of the States.

6. Relator Kimberlie Figg is a resident of Ozark, Missouri and is a former employee of Medtronic. Ms. Figg worked at Medtronic for nine years until February 18, 2011 and her title was Senior Diabetes Clinical Manager immediately prior to her resignation. Ms. Figg trained patients on how to use Medtronic insulin pumps and her territory for such training was Southwest Missouri and Northwest Arkansas. In addition to her training duties, Ms. Figg was

expected to assist Medtronic's sales team in selling replacement pumps to Medicare beneficiaries. Specifically, Ms. Figg was expected to make new prescriber sales calls and to generate at least two new pump referrals per week. To meet this goal, Medtronic required Ms. Figg to directly solicit patients on numerous occasions, both on the telephone, through iPro clinics, and through any other contact Ms. Figg may have had with patients.

7. Relator Tracy Garstka is a resident of Maumelle, Arkansas and is a former employee of Medtronic. Ms. Garstka worked at Medtronic for nine years and her title was Senior Diabetes Clinical Manager immediately prior to her resignation. Like Ms. Figg, Ms. Garstka trained patients on how to use Medtronic insulin pumps and her territory for such training was Eastern Arkansas and the "Boot Heel" area of Missouri. In addition to her training duties, Ms. Garstka was expected to assist Medtronic's sales team in selling replacement pumps to Medicare beneficiaries who have come out of warranty. Like Ms. Figg, Ms. Garstka was expected to make new prescriber sales calls and to generate at least two new pump referrals per week. Ms. Garstka was also required by Medtronic to directly solicit patients on numerous occasions, both on the telephone, through iPro clinics, and through any other contact Ms. Garstka may have had with patients.

8. Relators have personal, direct and independent knowledge of Defendants' submission of false claims to federal and state health care programs. Relators are the original and independent source of such information.

9. Medtronic, Inc. is a Minnesota corporation with its principal place of business at 710 Medtronic Pkwy., Minneapolis, MN 55432. Medtronic, Inc. may be served with this lawsuit by serving its registered agent, CT Corporation System, 350 N. St. Paul St., Dallas, Texas 75201.

10. Medtronic Minimed, Inc. is a Delaware corporation with its principal place of business at 18000 Devonshire St., Northridge, CA 91325. Medtronic Minimed, Inc. may be served with this lawsuit by serving its registered agent, CT Corporation System, 350 N. St. Paul St., Dallas, Texas 75201.

11. CCS Medical, Inc. is a Delaware corporation, transacts significant business in the northern district of Texas and may be served with this lawsuit by serving its registered agent, Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, DE 19808.

12. MiniMed Distribution Corp. ("Minimed") is a Delaware corporation and may be served with this lawsuit by serving its registered agent, CT Corporation System, 350 N. St. Paul St. Suite 2900, Dallas, TX 75201.

JURISDICTION AND VENUE

13. This *qui tam* action arises under the provisions of the Federal False Claims Act, 31 U.S.C. § 3729, *et seq.*, and similar false claims statutes of the States. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732 which specifically confer jurisdiction on this Court for actions brought under the False Claims Act.

14. Personal jurisdiction and venue for this action are predicated on 31 U.S.C. § 3732(a) which provides that "any action brought under § 3730 may be brought in any judicial district in which the defendant can be found, resides, transacts business or in which any act prescribed by § 3729 occurred." Defendants transact significant business in Dallas, Texas which is in the Northern District of Texas.

15. This Court also has supplemental jurisdiction over the *qui tam* claims brought on behalf of the States pursuant to 28 U.S.C. § 1367, which provides that "in any civil action of

which the district courts have original jurisdiction, the district court shall have supplemental jurisdiction over all claims that are so related to claims in action in such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution."

16. In accordance with the False Claims Act and this Court's order, this Complaint is to be filed *in camera*, remain under seal until at least June 12, 2012, and shall not be served on the Defendants until the Court so orders. On or about June 7, 2012, the Government filed an unopposed *Ex Parte* Application for the Extension of Time to Intervene, and requested this matter remain under seal. Relators have not received notice of the Court's Order on the Government's Application as of the date this Amended Complaint is filed, and therefore file it *in camera* and under seal.

17. As required under the False Claims Act, Relators have provided to the Attorney General of the United States and to the United States Attorney for the Northern District of Texas, a statement of all material evidence and information related to the Complaint. Such disclosure statement supports the existence of false claims by Defendants and possibly others in connection with Medicare, Medicaid and other federally-funded health care programs.

LEGAL BACKGROUND

Unsolicited Contact by DME Suppliers

18. Section 1834(a)(17) of the Social Security Act prohibits DME suppliers from directly soliciting Medicare beneficiaries regarding the furnishing of a covered item, except in three specific situations: (1) the beneficiary has given written permission to the supplier to make contact regarding the furnishing of a covered item; (2) the supplier has furnished a covered item to the individual and the supplier is contacting the individual only regarding the furnishing of

such covered item; or (3) the supplier has furnished at least one covered item to the beneficiary during the preceding fifteen months. 42 U.S.C. § 1395m(a)(17)(A); 42 C.F.R. § 424.57(c)(11). Prohibited direct solicitation includes "direct contact, which includes, but is not limited to, telephone, computer, e-mail, instant messaging or in-person contact, by a...supplier or its agents to a Medicare beneficiary without his or her consent for the purpose of marketing the..supplier's health care products or services or both." 42 C.F.R. § 424.57(a). Federal law specifically prohibits payment to a supplier who knowingly submits a claim generated pursuant to a prohibited solicitation. 42 U.S.C. § 1395m(a)(17)(B). Accordingly, any claims submitted as a result of unsolicited contacts are false and CMS shall exclude from Medicare any supplier that engages in a pattern of unsolicited contacts. 42 U.S.C. § 1395m(a)(17)(C); 68 Fed. Reg. 10255 (March 4, 2003).

19. As set forth in detail below, Medtronic has established an "Automated OOW Campaign"[2] which is also referred to by Medtronic as a "Patient Outreach Campaign" to make unsolicited telephone contacts to Medicare beneficiaries to solicit beneficiaries to purchase pumps and so that Medtronic can entice and coerce beneficiaries who currently use pumps into fabricating problems with the pumps so they can upgrade their pumps.[3] With regard to the latter, Medtronic flatly tells patients they should request a replacement pump because the beneficiaries are entitled to a new pump, even though the beneficiaries' current pumps are in perfectly good working order and meet the beneficiaries' medical needs. Upon the beneficiaries' agreement, Medtronic then submits or causes the submission of false claims for either a new pump or

[2] "OOW" is an acronym Medtronic uses that stands for "Out of Warranty."

[3] The "Patient Outreach Campaign" was in existence in some form or fashion when Relators' employment with MiniMed Distribution Corp. began. At that time, the scheme did not have a name assigned to it. Medtronic subsequently acquired MiniMed.

medically unnecessary replacement equipment. Each claim for reimbursement that results from such unsolicited contact is a false claim. In each case, Medtronic (1) has not received written permission from the Medicare or Medicaid beneficiaries to contact them; (2) is not contacting the beneficiary regarding a covered item previously furnished to the beneficiary by Medtronic;[4] and (3) has not furnished at least one covered item to the beneficiaries within the preceding fifteen months.

20. Relators also have firsthand knowledge that Medtronic's distributors, such as CCS, also illegally contact and solicit Medicare and Medicaid beneficiaries. This can happen in multiple ways. In some cases, Medtronic sends patient information to distributors, including CCS, and the distributors (including CCS) then contact the patients and directly solicit them in violation of 42 U.S.C. § 1395m(a)(17)(A) and 42 C.F.R. § 424.57(c)(11). In other cases, the distributors (including CCS) maintain a list of patients whose pumps are expiring and directly solicit them about upgrading to a new pump.

21. Furthermore, Medtronic and CCS have conspired to defraud the government through the submission of false claims. CCS is aware that Medtronic contacts Medicare beneficiaries through its "Patient Outreach Program" and then submits the leads generated from the "Patient Outreach Program" to CCS so that CCS can sell a pump to the beneficiaries. CCS welcomes and encourages such leads as they help increase CCS's sales.

Medicare Reimbursement

22. Medicare Part B is a federally subsidized, voluntary enrollment health insurance program. Part B pays a substantial portion of the health costs incurred by those enrolled in the

[4] Indeed, it is clear from Medtronic's practices and internal documents that the sole purpose of the "Patient Outreach Campaign" is to solicit new orders.,

Medicare program, including the costs of durable medical equipment ("DME") such as insulin pumps. 42 C.F.R. § 410.38(a). The Medicare program is administered by the Center for Medicare and Medicaid Services ("CMS").

23. Part B coverage extends only to those medical services that are medically "reasonable and necessary" for the beneficiary. 42 U.S.C. § 1395y(a); 42 C.F.R. § 411.15(k)(1). In order to administer, validate, and pay claims made under Part B, CMS contracts with regional, private insurance carriers who act as claims processors. 42 U.S.C. § 1395u. Upon receipt of a claim for payment, the claims processor or carrier decides whether the claimed services "were medically necessary, whether the charges are reasonable, and whether the claim is otherwise covered by Part B." *Schweiker v. McClure,* 456 U.S. 188, 191 (1982); *see also* 42 U.S.C. § 1395y(a). Among other requirements, Medicare will not pay a claim unless a physician certifies that the medical services are medically required and there must be information in the patient's medical record that supports the medical necessity for the item. 42 U.S.C. § 1395n(a)(2)(B); *Medicare Program Integrity Manual*, Chapter 5 – "Items and Services Having Special DME Review Considerations," § 5.7 (Centers for Medicare and Medicaid Services, December 31, 2008).

24. Providers such as Medtronic, and its distributors of insulin pumps, including CCS, ordinarily receive their Medicare reimbursements through an intermediary, who is bound by CMS's regulations and interpretive rules. *See Mercy Home Health v. Leavitt*, No. 03-6860, 2005 WL 579925 at *2 (E.D. PA 2005); *see also* 42 U.S.C. § 1395h; 42 C.F.R. § 421.100(h).

25. In order to aid Medicare participants and courts in interpreting what constitutes reasonable and necessary for the purposes of obtaining Medicare coverage, CMS issues manuals which include CMS's interpretation of the Medicare provisions of the Social Security Act and

the Code of Federal Regulations. *See Tucker v. Thompson*, No. 04-3934, 2006 W.L. 39644 at *3 (D. NJ 2006). These manuals do not, in and of themselves, have the effect of statutes and regulations. *United States of America ex rel. Suter v. Nat'l Rehab Partners, Inc.*, No. CV-03-015, 2009 W.L. 3151099 at *6 (D. ID 2009). However, "to adopt a position that interpretive rules are not binding would effectively nullify the Medicare manuals in their entirety and would allow defendants to submit claims for any and all types of non-covered services that clearly were not reasonable or necessary." *In Re Cardiac Devices Qui Tam Litigation*, 221 F.R.D. 318, 355 (D. Conn. 2004) (disagreeing with defendants' position that an interpretive rule cannot form the basis of a claim under the False Claims Act). In fact, there have been numerous cases imposing False Claims Act ("FCA") liability, and even criminal false claims liability, based on violations of Medicare manual provisions. *See, e.g., United States v. Weiss,* 914 F.2d 1514 (2nd Cir. 1990); *United States v. Mackby,* 261 F.3d 821 (9th Cir. 2001); *United States v. Larm,* 824 F.2d 780 (9th Cir. 1987), *cert. denied,* 484 U.S. 1078 (1988); *United States v. Calhoon,* 97 F.3d 518 (11th Cir. 1996).

Replacement of DME Must be Reasonable and Necessary

26. Federal law mandates that the reasonable useful lifetime of DME shall be equal to five (5) years, unless CMS establishes a different reasonable useful lifetime for particular DME. 42 U.S.C. § 1395m(a)(7)(C). If an item of DME paid for by Medicare has been in continuous use by the patient for the equipment's reasonable useful lifetime or if the carrier determines that the item is lost, stolen, or irreparably damaged, the patient may elect to obtain a new piece of equipment. 42 CFR § 414.210(f). However, any replacement pursuant to this regulation must be "reasonable and necessary" and may be reimbursed only when there is a new physician order and/or new Certificate of Medical Necessity which reaffirms the medical necessity of the

replacement DME. 42 U.S.C. § 1395y(a)(1)(A)-(B); *see also Medicare Benefit Policy Manual*, Chapter 15 – "Covered Medical and Other Health Services," § 110.2(C) (Centers for Medicare and Medicaid Services, August 20, 2010). "Medical necessity" is established when DME is "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). CMS has issued guidance on what is "reasonable and necessary" in Chapter 15 of its Medicare Benefit Policy Manual which provides in relevant part as follows:

> Although an item may be classified as DME, it may not be covered in every instance. **Coverage in a particular case is subject to the requirement that the equipment be necessary and reasonable for treatment of an illness or injury, or to improve the functioning of a malformed body member...Equipment is necessary when it can be expected to make a meaningful contribution to the treatment of the patient's illness or injury or to the improvement of his or her malformed body member**...Even though an item of DME may serve a useful medical purpose, the...intermediary must also consider to what extent, if any, it would be reasonable for the Medicare program to pay for the item prescribed. The following considerations should enter into the determination of reasonableness...**Does the item serve essentially the same purpose as equipment already available to the beneficiary**? Medicare Benefit Policy Manual, Chapter 15, § 110.1(C) (emphasis added).

27. In other words, replacing equipment that is in good working order and meets the beneficiary's medical needs is not necessary or reasonable because such replacement equipment would not "make a meaningful contribution to the treatment of the patient's illness." *Id.* Additionally, replacing equipment that is in good working order and meets the beneficiaries' medical needs is not reasonable or necessary since the replacement equipment serves the same purpose as the equipment already available and which is in good working order and used by the beneficiaries. CMS has issued guidance that states that "where an arrangement is motivated solely by a desire to create artificial expenses to be met by [Medicare] and to realize a profit thereby, such expenses would not be covered under [Medicare]. The resolution of questions

involving the disposition and subsequent acquisition of durable medical equipment must be made on a case-by-case basis." *Medicare Program Integrity Manual*, Chapter 5 – "Items and Services Having Special DME Review Considerations," § 110.4.

28. The scheme made the basis of this lawsuit is an example of an arrangement which is motivated solely by realizing a profit at Medicare's expense. Although Medtronic maintains a 24 hour emergency assistance hotline for beneficiaries to call in the event their pumps malfunction, Medtronic has initiated a "Patient Outreach Campaign" which has the purpose of illegally contacting Medicare beneficiaries immediately after the expiration of their insulin pumps' warranties (and in some cases before the expiration of the warranties) for the purpose of fabricating malfunctions with the beneficiaries' current pumps so that medical necessity can be established for replacement pumps and for enticing patients into a new pump. As CMS states in its Medicare Benefit Policy Manual, replacing DME is unreasonable when the replacement serves essentially the same purpose as the DME that is already available to the beneficiary. Medicare Benefit Policy Manual, Chapter 15, § 110.1(C). In the case of beneficiaries using Medtronic's pumps, the beneficiaries' current pumps are in good working order and meet the beneficiaries' needs and therefore a replacement is unreasonable because it serves the same purpose as the beneficiaries' current pumps. Furthermore, it is clear that Medtronic's "Patient Outreach Campaign" is nothing more than a thinly disguised attempt to create artificial expenses for the Medicare program so that Medtronic can realize profits. As set forth below, everyone wins with Medtronic's "Patient Outreach Program" except Medicare and Medicaid. Medicare beneficiaries receive a new pump, Medtronic, CCS and other distributors realize a nice profit and Medtronic and CCS's sales staff receive a commission on each replacement pump they sell, thus

incentivizing the sales staff to push for more sales. However, each time the government foots the bill.

DME Warranties

29. A DME supplier must "honor all warranties expressed and implied under applicable State law" and "**must not charge the beneficiary or the Medicare program for the repair or replacement of Medicare covered items or for services covered under warranty.**" 42 C.F.R. § 424.57(c)(6) (emphasis added). Medtronic's insulin pumps are under warranty for five (5) years from the date a beneficiary first starts using the pump.

30. As set forth in detail below, Defendants have repeatedly failed to honor the warranties on beneficiaries' insulin pumps for any malfunctions or other issues discovered during this five (5) year period. In fact, Defendants' own documentation shows many instances where, upon learning of malfunctions that are covered by warranty, Defendants put beneficiaries "on hold" or "close" beneficiaries' files until the expiration of the beneficiaries' warranties. Upon the expiration of the beneficiaries' warranties, Defendants contact the beneficiaries and submit a claim to Medicare or Medicaid for replacing the pumps, even though such pumps should have been replaced or repaired by Medtronic and at Medtronic's expense while under warranty. The numerous instances where a beneficiary has been put "on hold" until the expiration of their pump's warranty establishes that these instances are not rare, but rather that Medtronic has engaged in a pattern of behavior meant to reap profits for Medtronic at the expense of the federal government. The submissions of claims under these circumstances constitute false claims.

Federal Reimbursement: Anti-Kickback Statute

31. The federal health care Anti-Kickback Statute, 42 U.S.C. §1320a-7b, prohibits any person or entity from (1) knowingly and willfully making or causing to be made any false statement or representation of a material fact in any application for any benefit or payment under a federal health care program, (2) at any time knowingly and willfully making or causing to be made any false statement or representation of a material fact for use in determining rights to such benefit or payment, or (3) knowingly and willfully offering or paying any remuneration directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good or item for which payment may be made in whole or in part under a Federal health care program. 42 U.S.C. §1320a-7b(a)-(b). Under this statute, DME suppliers and distributors, including their employees or agents, may not falsely certify that their replacement equipment is medically necessary or artificially create medical necessity by misrepresenting to a beneficiary's physician and the federal government that a beneficiary's current equipment has malfunctioned or no longer meets the needs of the beneficiary. The Anti-Kickback Statute also prohibits DME suppliers from providing free items or services to referring physicians to induce the referring physicians to prescribe DME and the Anti-Kickback Statute prohibits DME suppliers from effectively waiving co-payments to induce Medicare and Medicaid beneficiaries to elect to receive replacement DME.

32. Any party convicted under the Anti-Kickback Statute must be excluded from federal health care programs for a term of at least five years. 42 U.S.C. §1320a-7(a)(1). Even without a conviction, if CMS finds administratively that a provider has violated the Anti-Kickback Statute, CMS may exclude that provider from the federal health care programs for a

discretionary period, and may impose administrative sanctions of $25,000 per kickback violation. 42 U.S.C. §1320a-7(b).

33. As set forth in more detail below, Medtronic has violated the Anti-Kickback Statute and the False Claims Act by, among other things, falsely certifying that its replacement equipment is medically necessary (even though its sales and field representatives making such certification have no medical background or expertise) and by artificially creating medical necessity by misrepresenting to a beneficiary's physician and the federal government that a beneficiary's current equipment has malfunctioned when in fact it has not and the current equipment continues to meet the beneficiary's medical needs. Medtronic has also violated the Anti-Kickback Statute by providing free items and services to patients, as well as to physicians and their practices. Such free items and services to physicians and physician practices include, but are not limited to, paying for lavish trips and all expenses to such destinations as California, Colorado and Dallas, providing free Medtronic licensed clinicians (such as RNs, RDs, and CDEs) to assist with the provision of clinical services at the physicians' offices, providing a continuous glucose monitoring system known as "iPro" to physicians for no charge that physicians have used to bill Medicare and Medicaid, providing free lunches, extravagant dinners and drinks to physicians (and in some cases their office staff) and providing patient information events where the sole purpose is to push the sale of pumps. Patients were likewise given free iPro monitoring tests.

34. Finally, Medtronic has a rebate program in place which has the sole purpose of remunerating Medicare and Medicaid beneficiaries seeking unnecessary pump replacements by off-setting the cost of the beneficiaries' co-pays for replacement pumps. Such rebates are

typically only offered after the beneficiary has declined the replacement equipment and is used as a last ditch effort by Medtronic to convince the beneficiary to elect to receive a replacement.

35. Relators have also personally witnessed CCS representatives providing kickbacks such as free lunches to doctors to push the sale of pumps. CCS representatives have a quota of pumps they have to sell on a monthly basis. To make sure they meet their quotas, CCS representatives provide free lunches in cooperation with Medtronic representatives and CCS representatives provide classes on diabetes where the main goal is to get Medicare and Medicaid beneficiaries to purchase an insulin pump and supplies from CCS. One CCS employee that has knowledge of these activities is Stacy Curzon.

36. Such violations of the Anti-Kickback Statute partially form the basis for Relators' False Claims Act claims. *See, e.g., McNutt v. Haleyville Medical Supplies, Inc.*, 423 F.3d 1256 (11th Cir. 2005) (holding that a violation of the Anti-Kickback Statute can form the basis for a quit tam action under the False Claims Act).

ALLEGATIONS AND FACTUAL BACKGROUND

Relators

Defendants' Scheme

37. Among other things, Medtronic manufactures and supplies insulin pumps to Medicare and Medicaid beneficiaries who suffer from diabetes. Medtronic sells most of its pumps to distributors, such as CCS, which then turn around and sell the pumps to Medicare beneficiaries. This type of business arrangement provides an incentive to both Medtronic and CCS to sell as many pumps as possible. In Medtronic's view, the more Medicare beneficiaries purchase pumps from distributors such as CCS, the more pumps the distributors will purchase from Medtronic. CCS and distributors turn around and sell the pumps to Medicare beneficiaries

and are then directly reimbursed by the government. So, CCS and other distributors are also incentivized to sell as many pumps as possible.

38. Defendants have figured out and implemented a scheme to increase their revenue by submitting and causing the submission of false claims to federal health care programs for replacement insulin pumps, as well as conspiring to submit or cause the submission of false claims to the government. Specifically, Defendants directly solicit Medicare and Medicaid beneficiaries to purchase Medtronic's pumps. This direct solicitation can be over the phone (e.g., Medtronic's "Patient Outreach Program"), through iPro clinics (which are discussed below), through "Technology Update" seminars where Medtronic directly solicits patients under the guise of informing them of changes in diabetic technology, or by distributors, such as CCS directly contacting the beneficiaries to convince them to purchase Medtronic's pumps.

39. By engaging in this scheme, Defendants engaged in a civil conspiracy to violate federal and state laws. Alternatively, Defendants engaged in a joint enterprise with a community of pecuniary interest toward the common purpose of violating federal and state laws. Pleading in the alternative, Medtronic, MiniMed, and/or CCS acted as the agent of one or more of the other Defendants.

Direct Solicitation

40. Some, but not all of the direct solicitation is directed towards patients that already have insulin pumps. Medtronic and its distributors, such as CCS, maintain a database of beneficiaries who use insulin pumps. Medtronic's database, among other things, lists the patient's name, physician, and a "status date" which is often the date a beneficiary's insulin pump goes out of warranty or a date a short time before or after the beneficiary's insulin pump goes out of warranty. Medtronic also maintains a list of beneficiaries who have pumps that are

out of warranty. Anyone listed on this list or in the database referenced above is known within Medtronic as an "Opportunity" and is given an "Opportunity ID" number (which is a different number than the Patient ID assigned to each beneficiary by Medtronic). In fact, for each patient contained in Medtronic's database, Medtronic efficiently lists next to each patient's name the "Opportunity Type" (which means what type of replacement equipment could be sold to the beneficiary) and the "Opportunity Status" (which quickly tells enterprising Medtronic sales representatives the status of obtaining a particular beneficiary's replacement equipment). Medtronic and CCS representatives conduct weekly "pipeline reviews." Additionally, Medtronic had access to a "CCS tracker" to check the status of pump sales to Medicare beneficiares.

41. On or about the "status date," Medtronic's sales representatives receive an "Automated OOW Campaign Lead Summary" which notifies them to contact beneficiaries with out of warranty insulin pumps. Medtronic's sales representatives also receive an "Out of Warranty" list containing the names and contact information for beneficiaries who have pumps that are no longer in warranty. Medtronic's sales representatives, who are paid a commission for each insulin pump they sell, contact the beneficiaries to initiate the process for replacing their insulin pumps or to initially sell beneficiaries an insulin pump. Medtronic slyly refers to its program of contacting beneficiaries as its "Patient Outreach Campaign" and such program in the past has also been called an "OOW Campaign" ("OOW" stands for "out of warranty"). The stated goal of the "Patient Outreach Campaign" is to educate the beneficiary of the "benefits of having a pump in warranty;" however, as evidenced by Medtronic's own documents, the "Patient Outreach Campaign" is nothing but a thinly disguised attempt to sell new or replacement pumps to beneficiaries.

42. Medtronic's distributors, such as CCS, also directly solicit Medicare and Medicaid beneficiaries to purchase pumps. Once a beneficiary agrees to receive a pump, whether a new or replacement pump, Medtronic refers the beneficiary to a distributor such as CCS. The distributors then contact the beneficiary to directly solicit the beneficiary and to "seal the deal." For most of the Medicare beneficiaries contacted by CCS, CCS has no prior relationship with the beneficiary. At least once a week, Medtronic's representatives conduct what is known as a "pipeline review" of patients with CCS representatives to make sure no Medicare beneficiary is missed. In fact, Medtronic sales representatives are told by their managers to "partner with your CCS representative" as they are "another pair of feet on the street." Medtronic's managers tell their sales representatives that they are "missing the boat" if they are not working with their CCS "partner" in selling new and replacement pumps.

43. Medtronic's direct solicitation of beneficiaries under the "Patient Outreach Campaign" and CCS's direct solicitation of beneficiaries violates federal law, specifically 42 U.S.C. § 1395m(a)(17)(A) and 42 C.F.R. § 424.57(c)(11), because (1) they do not have beneficiaries' written permission to contact them, (2) they are not contacting the beneficiaries only regarding the furnishing of the beneficiaries' current insulin pumps, and (3) they have not furnished at least one covered item to the beneficiaries during the preceding fifteen months of the unsolicited contact. CCS, as well as some of Medtronic's other distributors know that the leads generated by Medtronic and sent to them are generated from direct solicitation in violation of 42 U.S.C. § 1395m(a)(17)(A) and 42 C.F.R. § 424.57(c)(11). Federal law specifically prohibits payment under these circumstances. 42 U.S.C. § 1395m(a)(17)(B). Accordingly, any claims submitted as a result of unsolicited contacts are false. 42 U.S.C. § 1395m(a)(17)(C); 68 Fed. Reg. 10255 (March 4, 2003).

44. There are numerous instances of illegal direct solicitation and medically unnecessary insulin pump replacements which have been paid for by a federal health care program which are evidenced from Medtronic's own documents. In fact, all patients in the "Patient Outreach Program" are directly solicited by Medtronic or its distributors at some point, whether it is to obtain their first replacement pump, or a second, third or subsequent replacement pump. Here are just a few examples (many more exist) of (1) illegal direct solicitation by Medtronic and CCS; (2) the conspiracy between Medtronic, CCS and/or MiniMed; (3) medically unnecessary replacements that resulted in claims being made to federal health care programs; and/or (4) attempts to bill Medicare for medically unnecessary replacements:[5]

- Medicare Beneficiary Jane Doe I: This beneficiary's pump went out of warranty on June 1, 2010. On June 1, 2010, even though the pump was still under warranty, Medtronic contacted the beneficiary and started the pump replacement process even though the pump still worked properly and the pump was under warranty. In its records, Medtronic listed the following as reasons for the replacement: "crack in casing, scratches on screen, rec'd motor error and no delivery alarms." Defendants subsequently submitted or caused the submission of a claim to Medicare for the replacement pump even though the malfunctions were noted while the pump was still under warranty.

- Medicare Beneficiary Jane Doe II: This beneficiary's pump went out of warranty on January 17, 2011. Medtronic contacted the beneficiary on February 1, 2011 and started the replacement process even though the beneficiary's pump still worked properly. The stated reasons for needing a replacement were that the beneficiary was "changing batteries more frequently 4-6 weeks, screen slightly scratched." Medtronic's notes even stated that the "pump is working ok." Medicare paid to replace this good pump.

- Medicare Beneficiary Jane Doe III: This beneficiary's pump went out of warranty on February 10, 2011. The same day, Medtronic directly solicited

[5] For privacy purposes, Relators are not disclosing the identity of these Medicare beneficiaries in this Complaint. Relators have disclosed these Medicare beneficiaries' names, contact information, as well as other claim information to the United States Government and the States in their Written Disclosure.

the beneficiary and replaced her pump at Medicare's expense just because her old pump had "scratches on the display screen."

- Medicare Beneficiary Jane Doe IV: The beneficiary's pump went out of warranty on July 30, 2009. The same day, Medtronic contacted the patient and noted some "malfunctions" that should have been covered under Medtronic's warranty. Instead, Medtronic caused the submission of and CCS submitted a false claim for a new pump to Medicare.

- Medicare Beneficiary John Doe I: Medtronic's "Patient Outreach Campaign" notified a sales representative to contact this beneficiary on December 28, 2009. Medtronic's sales representative noted that the pump was still in warranty and put in Medtronic's notes to put the file "on hold until oow." One day after the pump went out of warranty, Medtronic took the file off "hold" and contacted the beneficiary. Several "malfunctions" were noted one day after the pump went out of warranty and a new pump was sent to this beneficiary and paid for by Medicare.

- Medicare Beneficiary Jane Doe V: Relator Tracy Garstka contacted this beneficiary on February 4, 2011 after another Medtronic sales representative started the process to replace this beneficiary's perfectly good pump. During this telephone conversation, the beneficiary agreed that her pump was working okay and that there was no malfunction on her pump. Medtronic contacted this beneficiary one day after her warranty expired and Defendants caused the submission or submitted a false claim to Medicare for replacing her pump.

- Medicare Beneficiary Jane Doe VI: This beneficiary's physician wanted to replace the beneficiary's pump while it was in warranty due to problems the patient was having with the pump. Instead of honoring its warranty, Medtronic put the file on hold and noted that it would contact the beneficiary when the pump went out of warranty. One day after the pump's warranty expired, Medtronic directly solicited the beneficiary, noted certain malfunctions with the pump and Defendants caused the submission or submitted a claim to Medicare to replace the beneficiary's pump.

- Medicare Beneficiary Jane Doe VII: The beneficiary's pump went out of warranty on December 8, 2010. One day before the pump's warranty expired, Medtronic contacted the beneficiary and convinced her to replace her pump. Defendants subsequently submitted or caused the submission of a claim for the replacement of this pump as soon as this beneficiary's pump went out of warranty.

- Medicare Beneficiary Jane Doe VIII: This beneficiary's pump went out of warranty on February 7, 2009. After not hearing from her, Medtronic's

Patient Outreach Campaign contacted the beneficiary. The stated "goal" of the contact was "to educate the patient on the benefits of having a pump in warranty." After succeeding in its goal of "educating" this beneficiary, Medtronic created bogus "malfunctions" of the beneficiary's current pump and Defendants subsequently submitted or caused the submission of a claim to Medicare to pay for a replacement pump.

- Medicare Beneficiary John Doe II: This beneficiary's pump went out of warranty on December 8, 2010. Medtronic's "Patient Outreach Campaign" dutifully contacted this beneficiary the next day when the beneficiary reported that his current pump was "working well, no malfunctions." Despite the fact that this beneficiary's pump had no malfunctions and was working well, Medtronic's sales representative "went over the features of the Revel briefly." The beneficiary was convinced to accept a replacement soon after and a false claim was submitted to Medicare.

- Medicare Beneficiary John Doe III: Medtronic noted that this beneficiary had been out of warranty since 2008 and attempted to contact him on February 11, 2011. The beneficiary said that nothing was wrong with his current pump. Despite this, Medtronic noted in its system that it "went over the malfunction questions." Medtronic asked the beneficiary to "call in when he sees any malfunctions now that he is oow [out of warranty]." Medtronic's enterprising sales representative also noted in Medtronic's system that he "went over new features of the [replacement pump] as well." While no false claim was submitted on behalf of this beneficiary, Medtronic's records related to this beneficiary show a pattern of submitting false claims to Medicare.

- Medicare Beneficiary Jane Doe IX: This beneficiary's pump went out of warranty on November 2, 2010. Medtronic contacted this beneficiary the same day to "proceed with the upgrade process." Medtronic noted that the beneficiary was "having issues with current pump." Defendants subsequently submitted or caused the submission of a claim to Medicare to pay for the new pump.

- Medicare Beneficiary John Doe IV: This beneficiary's pump went out of warranty and Medtronic contacted him to replace his pump. Medtronic noted that the beneficiary was "very stern saying that he and [his doctor] are very happy with the 508," which was his current pump. To Medtronic's dismay, no false claim was submitted to the federal government.

- Medicare Beneficiary Jane Doe X: Medtronic contacted this beneficiary before her pump expired and put her "on hold until oow." One day after her warranty expired, Medtronic contacted the beneficiary to replace her pump. The beneficiary was unhappy with Medtronic contacting her and Medtronic noted in its system that the beneficiary "states pump is working well and has

already rcvd numerous phone calls about [upgrading] not ready to proceed and will call us when she is ready." To Medtronic's dismay, it could not submit a false claim for this beneficiary.

- Medicare Beneficiary Jane Doe XI: Medtronic initially contacted this beneficiary to initiate a replacement prior to the expiration of her warranty. Upon discovering that her pump was still under warranty, Medtronic noted that the file was "on hold until oow" or on hold until the pump was out of warranty. Medtronic contacted this beneficiary one day after her warranty expired and Defendants subsequently submitted or caused the submission of a claim to Medicare for replacing her pump even though her old pump still worked properly.

- Medicare Beneficiary Jane Doe XII: This beneficiary's pump went out of warranty on February 11, 2011. Despite this, Medtronic contacted the beneficiary on February 10, 2011 (one day before the pump's warranty expired) to initiate the replacement process. There was no medical necessity for this replacement and Defendants subsequently submitted or caused the submission of a claim to Medicare which paid for the replacement.

- Medicare Beneficiary John Doe V: This beneficiary's pump went out of warranty on January 26, 2011. Medtronic contacted this beneficiary the same day and Defendants subsequently submitted or caused the submission of a claim for a replacement at Medicare's expense even though there was no malfunction with his current pump.

- Medicare Beneficiary Jane Doe XIII: This beneficiary's pump went out of warranty on December 27, 2010. Notwithstanding, Defendants shipped her a new pump prior to the expiration of the warranty on November 24, 2010 and submitted a claim to Medicare for payment.

- Medicare Beneficiary Jane Doe XIV: This beneficiary's insulin pump went out of warranty on June 29, 2010. While the pump was still in warranty, Medtronic contacted the beneficiary and noted in Medtronic's computer system to call the beneficiary back after the warranty expired. One day after her pump went out of warranty, on June 30, 2010, Medtronic contacted this Medicare beneficiary and started the replacement process due to the fact that the beneficiary's pump had "scratches" and its "battery life [was] diminished." Defendants subsequently submitted or caused the submission of a claim to Medicare which paid for the new pump.

- Medicare Beneficiary John Doe VI: Medtronic contacted this beneficiary on June 3, 2010 and the beneficiary stated there was nothing wrong with his pump, but that he would like to upgrade in September. Medtronic told the beneficiary that it would contact him back in September. Medtronic contacted

this beneficiary in September, fabricated malfunctions with his pump and Defendants subsequently submitted or caused the submission of a claim to Medicare for the replacement pump.

45. These are just a few examples of Defendants' repeated False Claims Act violations which were taken from a small time frame in 2010. Many more examples exist as this practice was ongoing during Relators' entire employment with MiniMed and Medtronic. Each of the above beneficiaries was contacted in violation of 42 U.S.C. § 1395m(a)(17)(A) and 42 C.F.R. § 424.57(c)(11) for a pump replacement. It should be noted that Defendants also contact other Medicare and Medicaid beneficiaries that do not currently use pumps to directly solicit those patients in violation of 2 U.S.C. § 1395m(a)(17)(A) and 42 C.F.R. § 424.57(c)(11). These beneficiaries are identified through iPro clinics (discussed below), "Technology Update" seminars, "Now You Can"[6] classes and through other various surreptitious methods.

False Claims for Replacement Pumps

46. As a part of the "Patient Outreach Campaign," and as evidenced by the patients listed above, Medtronic's sales representatives scare the beneficiaries into thinking they need a new pump and assist the beneficiaries in fabricating reasons why their pumps are allegedly damaged beyond repair. Interestingly, none of the beneficiaries contacted by Defendants call Medtronic's 24 hour helpline indicating or claiming their pump is malfunctioning. Curiously, directly after receipt of the call from Defendants' sales representatives, such beneficiaries are requesting and CCS and other Medtronic distributors are eagerly submitting claims or causing the submission of claims to Medicare and Medicaid for new pumps. When submitting such

[6] "Now You Can Classes" are classes or seminars put on by Medtronic sales representatives for diabetic patients. The main purpose for the classes are to identify potential pump candidates and to directly solicit them to purchase a pump.

claims, Medtronic and its distributors (including CCS) represent that the beneficiaries' old pumps no longer function or meet the beneficiaries' medical needs. Often times, when contacted by Medtronic's sales representatives, beneficiaries convey that their pump is working properly. Not to be deterred, Defendants' persistent sales representatives tell the beneficiaries that they are automatically entitled to new insulin pumps after five years and that Medicare pays for the pumps "no questions asked." In reality, and as evidenced by a recent e-mail from Medtronic's Vice President of US Sales, Medtronic's sales representatives know that they must show medical necessity for a replacement pump and often times they embellish minor issues with a beneficiary's current pump or create non-existent "malfunctions" to artificially create medical necessity for a replacement. Such minor issues which allegedly substantiate medical necessity include "minor scratches" on a screen or other "issues" that may be fixed for significantly less than the cost of a replacement.

47. Some of the common stated malfunctions or reasons for a replacement pump input in Medtronic's system (along with the reason why such "malfunction" or reason is bogus) include:

- "Insulin squirting out of cannula when priming." This is a normal operating occurrence of the pump and is in fact a part of the priming process.
- "Diminished battery life" or "battery life shortened to about 3 weeks." Three weeks is actually longer than the expected battery life. Medtronic's 24 hour helpline tells Medicare beneficiaries that a 7 to 11 day battery life is typical for someone taking about 40 units of insulin per day (which most patients take). Additionally, the pumps' user guide states that a "short battery life does not mean that something is wrong with [a] pump."
- "Battery cap worn." A battery cap is easily replaced for a few dollars and the cap does not affect the pump's ability to function.
- "Motor is noticeably louder" or "grinds." This does not affect a pump's operation.

- The patient "has to prime more than once." This problem arises from the patient's failure to connect the tubing properly and is not an indication that pump is not functioning properly.

- "A lot more air in the tubing." This is a patient-generated problem when the patient fails to get all of the air bubbles out of the reservoir. This is not a problem with the pump.

- "Basals needs to be .025." According to Relators, someone that needs such fractional increments of insulin delivery would be called "insulin sensitive", meaning that a very tiny amount of insulin changes their blood glucose significantly. According to Relators, this is rarely seen in adults and instead is quite common in pediatric populations. The adult diabetic Medicare population is about 90 percent Type 2 Diabetes and usually very "insulin resistant." Therefore, Medicare beneficiaries most often need larger amounts of insulin per hour (basal insulin) at rates that commonly range from 0.5 - 2.0 units per hour to change their blood glucose at all. Insulin resistance is a classic characteristic of Type 2 diabetes so the "need" for 0.025 basal rate as a reason to upgrade these patients is bogus and a Medtronic sales representative without any clinical background is not qualified to document this need.

- "Patient is forgetting to bolus after a meal." According to Relators, the term "bolus" refers to the dose of insulin that patients would take to cover the food they eat. This is done by them doing a few button pushes which makes the pump give them the appropriate amount of insulin to "cover" their food. According to Relators, forgetting to take a bolus would be equivalent to a diabetic that takes insulin shots simply forgetting to take their shot when they ate. The replacement pump has a new feature on it that you can set alarms to remind you to take your bolus. This new feature is not medically necessary. According to Relators, there are many physicians that tell their patients that because the insulin is rapid acting, it is okay to wait and bolus after they eat. As a matter of fact, the newer fast acting insulin called Apidra, actually states in the label information that it is okay to bolus after eating providing more flexibility. Therefore, needing a missed meal bolus "reminder" feature is not a medical necessity.

- "Patient needs a 522 for the adjustable active insulin curve for better control and insulin dosing." If a patient needs this feature it would need to be a documented change in medical necessity from their physician, not from an unlicensed Medtronic sales representative.

- "No Delivery Alarm." According to Relators, this issue can be easily fixed in most cases and just means that the patient's tubing is kinked and the insulin cannot infuse through. The patients simply need to change the site where the insulin is injected.

48. Using bogus reasons or malfunctions like the examples above, Medtronic's sales representatives, who do not have any clinical background and are not licensed to practice

medicine, determine that a replacement is medically necessary. Such determination is improper. *See* 42 U.S.C. § 1395n(a) (payment for services should be made only if a physician certifies such services were medically required); *see also, e.g., United States v. Miller*, 607 F.3d 144 (5th Cir. 2010) (stating that it is improper for a DME supplier to make "the key decision whether a particular patient had a medical need" for DME). After making the determination that a replacement pump is medically necessary for a beneficiary, Medtronic's sales representatives or Medtronic's distributors (including CCS) create a Certificate of Medical Necessity and submit the Certificate of Medical Necessity to the beneficiary's physician where the physician signs the Certificate of Medical Necessity without verifying the beneficiary's pump has malfunctioned and without receiving an explanation why the beneficiary is receiving a new pump. In other words, Medtronic and its distributors such as CCS falsely represent to beneficiaries' physicians that the pumps are broken or malfunctioning and therefore Medtronic and its distributors are the only parties that certify to the medical necessity of a replacement pump. This violates federal law as Medicare will not pay a claim unless a physician certifies that the medical services are medically required. 42 U.S.C. § 1395n(a)(2)(B). In an attempt to further justify and document medical necessity for each pump replacement, in addition to creating a Certificate of Medical Necessity, Medtronic, and sometimes the distributor, sends each beneficiary a "Warranty Update" document which the beneficiary fills out purportedly to justify the replacement.

49. Finally, it should be noted that Medtronic maintains a 24 hour helpline for recipients of its pumps. This helpline provides immediate assistance in the event a pump malfunctions. In the event a Medicare beneficiary has a real malfunction with his or her pump, the beneficiary could contact the helpline. Each of the beneficiaries listed above could have contacted the helpline to report their "malfunctions." However, they did not contact the helpline

because their current pump was functioning properly and meeting their medical needs. Only after receiving a call from a Medtronic sales representative through the "Patient Outreach Program" did a malfunction occur which required a completely new pump.

50. Realizing that Medtronic has been submitting false claims and Medtronic's potential liability for its scheme, certain Medtronic personnel have recently issued guidance to Medtronic's sales representatives so that Medtronic's fraudulent scheme is not as obvious. On January 31, 2011, Mike Gill, Medtronic's Vice President of US Sales sent an e-mail to Medtronic's sales team (among others) discussing replacement pumps. Below are relevant excerpts from Mr. Gill's e-mail:

> *I would like to take a moment to reemphasize the importance of balancing the drive for sales with the importance of accuracy, integrity, and long-term relationships with our payors and HCP partners. Recently, we have received complaints from payers (and patients) that some upgrades for out-of-warranty pumps were unnecessary, including allegations of fabricated malfunctions. Inside Sales leadership and Legal have reviewed recorded calls with patients, DTC notes in our system, DTA summaries in CMNs, and field based OOW leads, and found that some upgrade claims were not supportable. In these cases the actual pump malfunctions were exaggerated or assumed, and did not accurately represent the information given by patients. In each case, we have rescinded the claim and/or refunded the payer, and acknowledged error on Medtronic's part...any upgrades that are based on fabrication, exaggeration, or a disregard for what the patient actually stated, cannot be tolerated...To support an upgrade, you must have enough information to show a legitimate malfunction exists. For example, a patient simply answering "yes," "sometimes," or "I think so" to questions about bad alarms, buttons, battery, screen, or any other pump issue is NOT enough...In other words, the patient's statements must support a malfunction that prevents or inhibits normal pump operation...If a malfunction exists but the pump is still in warranty, you must refer the patient to the 24-hour helpline for assistance. Purposefully waiting or creating delay until the warranty period expires is unacceptable and will not be tolerated...The statement or idea that patients "can get a new, covered pump every 4 or 5 years" is generally FALSE. Upgrades are supportable only if (i) a legitimate malfunction exists, or (ii) there is a clinical, medically necessary justification for a new pump...*

51. This e-mail shows that Medtronic realizes that false claims have been submitted as a result of its "Patient Outreach Campaign." Disturbingly, the false claims continue despite Mr. Gill's e-mail. The "Patient Outreach Campaign" continues to illegally solicit patients. In fact, to reduce the likelihood that Medicare would grow suspicious of its practices and "Patient Outreach Campaign," after receiving Mr. Gill's e-mail, Relators' supervisors told Relators and Medtronic's sales representatives not to contact patients immediately after a beneficiary's pump goes out of warranty, but to wait a few weeks to a month "so that it is not obvious" to Medicare. Additionally, some of the false claims listed above submitted for replacement pumps show that Medtronic's scheme continues and is encouraged by team leaders, despite Mr. Gill's e-mail.

Additional Practices Resulting in False Claims

52. On top of the false claims discussed above, Medtronic has engaged in other practices to cause the submission of false claims. Occasionally, physicians or their practices will conduct training for a Medicare or Medicaid patient on his or her pump once it is received. Medtronic has taught physicians and physician practices to bill Medicare and Medicaid a higher E&M code for their extended office visit in this situation. E&M codes are based on the length of face-to-face time with a patient so Medtronic has "taught" these providers that instead of becoming contracted with Medtronic to receive reimbursement for the training, they will make more money by billing Medicare and Medicaid higher level E&M codes.

53. Additionally, Medtronic has inappropriately taught physicians and physician practices to bill Medicare and Medicaid by using DSMT codes for insulin pump training. The American Association of Diabetes Educators defines DSMT as the following educational topics (which is the industry standard): healthy eating, being active, glucose monitoring, taking medication, problem solving, healthy coping and reducing risk. To bill for DSMT training, a

provider must have provided training on these topics. Physicians and physician practices have been "taught" by Medtronic to bill Medicare and Medicaid by using these codes for insulin pump training (which is not a DSMT topic) so that Medtronic is not getting billed for the training. Medtronic has also inappropriately encouraged dietitians to bill Medicare and Medicaid by using the "MNT" Medical Nutrition Therapy codes and physicians and Nurse Practitioners bill Medicare and Medicaid by using E&M codes for pump training. Moreover, Medtronic contracts with diabetes centers and "certified pump trainers" to provide training and Medtronic reimburses the centers and trainers for this training. Recently, Medtronic has wanted to cut its certified pump trainer budget and has instructed trainers to bill Medicare and Medicaid by using certain billing codes instead of sending Medtronic a bill for the training, even though the billing codes are not for training and Medtronic knows this billing practice is improper. The goal of these recommendations by Medtronic is for Medicare and Medicaid to pick up the tab for training patients, instead of Medtronic.

54. Another practice Medtronic has engaged in that has resulted in numerous false claims relates to its manipulation of C-Peptide Tests. In order for insulin pumps to be deemed medically reasonably and necessary for the treatment of diabetes, CMS has set forth certain requirements which must be met. Specifically, among other requirements, a patient must meet the updated fasting C-Peptide testing requirement which is contained in the National Coverage Determination for Infusion Pumps. In the National Coverage Determination for Infusion Pumps, the updated fasting C-Peptide testing requirement is defined as follows:

- Insulinopenia is defined as a fasting C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory's measurement method.
- For patients with renal insufficiency and creatinine clearance (actual or calculated from age, gender, weight, and serum creatinine) ≤50 ml/minute, insulinopenia is

defined as a fasting C-peptide level that is less than or equal to 200% of the lower limit of normal of the laboratory's measurement method.

- Fasting C-peptide levels will only be considered valid with a concurrently obtained fasting glucose $\leq$225 mg/dL.
- Levels only need to be documented once in the medical records.[7]

55. Medtronic encourages its employees to teach physicians and physician practices to manipulate this test to ensure that a pump candidate meets these requirements. Specifically, Medtronic employees encourage and educate physicians and/or physician practices that in order to meet Medicare requirements, the physician or their staff should inject pump candidates, or have the pump candidates inject themselves, with exogenous insulin prior to the C-Peptide test to ensure the test results meet Medicare's updated fasting C-Peptide testing requirement.[8] The exogenous insulin dose is known not to be detected in the lab tests and helps to ensure that the patient's blood sugar will be low enough to meet the Medicare required levels necessitating an insulin pump. To further ensure that the patient will meet the Medicare requirements necessitating an insulin pump, Medtronic has educated physicians and physician practices that once the exogenous insulin is administered, the patient should walk up and down the physician's hallway for period up to a half hour to increase the patient's heart rate, improving the absorption rate of the exogenous insulin and ensuring that the patient's blood sugar is lowered. In other words, Medtronic is purposefully manipulating patient test results to meet Medicare requirements so that Medicare will determine a pump is medically necessary for a patient and ultimately order an insulin pump from Medtronic or CCS. Due to Medtronic's encouragement,

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[7] *See* Medicare's National Coverage Determination for Infusion Pumps, Chp. 1, § 280.14. This CMS Manual can be found at https://www.cms.gov/manuals/downloads/ncd103c1_Part4.pdf.

[8] In fact, at times Medtronic representatives call Medicare and Medicaid beneficiaries and advise the patients to take an injection prior to the test.

guidance and education, this practice is common place and is often utilized by many prescribing physicians. In fact, Relators have firsthand knowledge that that the patients of Arkansas Diabetes Clinic and Research Center in Little Rock, Arkansas and White River Diagnostic Clinic in Batesville, Arkansas follow this procedure. Relators were present during a conversation between Mike Gill, a Medtronic Vice President of Sales, and a physician of Arkansas Diabetes Clinic and Research Center and other Medtronic managers where this practice was discussed and encouraged by Mr. Gill. Relators also have had a telephone conversation with the Territory Manager of Western Arkansas regarding his role in supporting such practice.

Anti-Kickback Violations

56. Medtronic has violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, in the following respects.

a. For more than nine years, Medtronic has had a program in place for its top-referring physicians, new prescribers and their practices called "Nurse in the Office Day" under which Medtronic's employees go to the physicians' offices and provide services to the physicians without charge to the physicians. The services provided by Medtronic employees during "Nurse in the Office Day" include training patients on the use of Medtronic pumps and openly reviewing all of the physicians' medical records to identify patients that are potential pump candidates. As of the date Relators' employment ended with Medtronic, this program was still ongoing. Medtronic's aim with "Nurse in the Office Day" is to generate prescriptions for Medtronic's products, including new and replacement pumps. Relators were required to participate in "Nurse in the Office Day" and have firsthand knowledge of the types of services provided to physicians free of charge. This service is a reward and an incentive for those physicians who significantly prescribe Medtronic's pumps and is used as a tool to gain access to **new** prescribers' patients who could be potential OPPS (potential pump candidates). Additionally, physicians also bill Medicare and Medicaid for services provided by Medtronic's employees, reaping a double benefit where they receive an employee for their practice free of charge and then bill Medicare or Medicaid for the clinicians' services as though they were provided by employees of their practice. Many examples of physicians and practices that have received this free service exist. Ms. Figg conducted "Nurse in the Office Day" for the following physicians: Nibia Rodriguez, M.D. (Bentonville, Arkansas), Adam Maass, M.D. (Bentonville, Arkansas), and Jasbir Dhawan (Joplin, MO), among

others. Ms. Garstka conducted "Nurse in the Office Day" for the following physicians or practices: Kevin Ganong (Jonesboro, AR) and White County Diagnostic Clinic (Batesville, Arkansas), among others. Interestingly, for Dr. Ganong's practice, even though Ms. Garstka provided the services, the practice would still bill Medtronic for the training. In other words, Medtronic was effectively paying this practice to prescribe its pumps.

b. Medtronic provides a continuous glucose monitoring system known as "iPro" to physicians for no charge that physicians often use to bill Medicare and Medicaid. In fact, Relators were expected to provide a minimum of three ***free*** iPro clinics per month to physicians with a least four patients per clinic. Medtronic requested that physicians choose multiple daily injection ("MDI") patients for the free clinics. Medtronic's employees, including Relators, would then come into the physician's office and hook the patient onto the iPro. Medtronic's employees would then retrieve the iPro from the patient three days later and download information from the iPro into reports for the patients' physicians. Medtronic's goals for these free clinics are to (1) show the physicians that these patients need a Medtronic insulin pump which quite often results in a prescription for a Medtronic pump; (2) sell the physicians the iPro system; and (3) identify potential **new** pump candidates (commonly referred to within Medtronic as "OPPS") that Medtronic could directly solicit. Because the iPro clinics have been so successful in identifying "OPPS," Medtronic's managers refer to the iPro as the "pump finder." Relators were required to submit weekly reports to their managers that included the names of patients using the iPro, the patients' phone numbers, and the number of shots the patient took each day. Medtronic provides and will continue to provide free iPro clinics to physicians as long as the clinics yield "OPPS."[9] Relators are also aware of several instances where physicians bill Medicare and Medicaid for Medtronic's free clinics, even though the physicians did not provide any services and even though the iPro used to provide the services was owned by Medtronic and not the physicians. An example of a physician group that has received free continuous glucose monitoring systems from Medtronic is Poplar Bluff Internal Medicine Clinic in Poplar Bluff, Missouri. Many more exist. Relators are aware of several Medtronic representatives that provided free systems to physicians and their practices, including Susie Corrigan in Kansas City, Missouri and Mike Price. Relators have also provided free iPro clinics to Harold Blankenship (Joplin, MO), Mary Ann Mugo (Branson, MO), Searcy Internal Medicine (Searcy, AR), among others. These iPro clinics are

[9] In fact, Relators are aware of several physicians that disapprove of Medtronic's practices with regard to the iPro clinics and can testify about this practice. One such physician is Greg Ledger, M.D. out of Springfield, Missouri. Dr. Ledger has insisted for years that Medtronic quit soliciting his patients and became angry when Medtronic told him the purpose of their iPro clinics. Another physician group who refuses to allow Medtronic to engage in this practice is Little Rock Diagnostic Clinic in Little Rock, AR. The physicians in this group do not prefer to prescribe Medtronic's pumps because of Medtronic's practice of soliciting their patients without their permission, even though the physicians have repeatedly requested that Medtronic desist from direct solicitation.

another example of an illegal direct solicitation because Medtronic is using the clinics to directly solicit beneficiaries to purchase pumps. Therefore, any claims resulting from these clinics are false claims.

c. Medtronic has a rebate program in place which has the sole purpose of remunerating Medicare and Medicaid beneficiaries seeking unnecessary pump replacements by off-setting the cost of the beneficiaries' co-pay for replacement pumps. Under this rebate program, a beneficiary is entitled to a $500.00 rebate in the event the beneficiary agrees to obtain a replacement pump and return their old pump to Medtronic for refurbishment. The rebate is only offered to beneficiaries that refuse to obtain a replacement pump either because their old pump still meets their needs or the co-payment, which is usually $1,100 - $1200, is too much for them. The rebate program is used and implemented by Medtronic as a way to seal the deal or provide an incentive to beneficiaries that would not otherwise request a replacement.

d. Medtronic has taken various physicians and their practices to various destinations free of charge as a reward for their prescriptions. Some examples include:

i. In the Summer of 2002, Medtronic paid for a pediatric endocrinologist and her nurse to travel to a conference in Keystone, Colorado. Ms. Figg accompanied this high-prescribing physician and her nurse and they stayed at the Keystone Resort. During this trip, Medtronic covered the bills for numerous expensive meals, a tour of the Coors Brewery and even picked up the tab for the physician to FedEx some large rocks home from Keystone for the physician's garden.

ii. On March 8, 2008, Ms. Figg took a large prescriber on a "customer visit" to Medtronic's plant in Los Angeles. During this trip, Medtronic rented a convertible for the prescriber, covered the prescriber's hotel expenses and paid for all of the prescriber's meals, most of which were extremely nice meals.

iii. From March 13-17, 2008, Ms. Figg took a physician, her nurse practitioner, an office manager and a medical assistant to Los Angeles for a "customer visit." Medtronic covered all of the costs for this trip, including airfare, hotel, tours of Hollywood, and expensive dinners on the beach.

iv. In June of 2008, Ms. Figg took the nurse of a large prescriber on a "customer visit" to Medtronic's plant in Los Angeles because the nurse had influence on which pump a patient would be prescribed. During this trip, Medtronic again paid for all expenses which included expensive dinners on the beach and drinks.

v. On May 13, 2010, Ms. Figg took a Diabetes Educator on a "customer visit" to Los Angeles. Ms. Figg's instructions were to "schmooz" the educator and make her a Medtronic advocate because she works with key prescribers such as Sean Hamlett, M.D. Medtronic covered the cost for a limo ride, expensive dinners on the beach, large bar tabs, hotel expenses at the Hotel Palomar and air fare.

vi. On December 3, 2010, Ms. Figg took several pump prescribers and their staff on a trip to Los Angeles. During this trip, Medtronic paid for extremely large dinner bills from nice restaurants on the beach, tours of Hollywood, hotel, and air fare.

57. Additionally, Defendants continue to violate the Anti-Kickback Statute by providing free lunches and extravagant dinners to physicians and patient information events where the only goal is the sale of Medtronic's insulin pumps. Relators have firsthand knowledge that Medtronic employees Jason Cooper and Greg Veazey sometimes regularly treat high-prescribing physicians to expensive dinners to reward them for their prescriptions of Medtronic's pumps. An example of a physician regularly treated to such dinners is Teresa Nimmo, M.D.

58. As set forth above, Relators have also personally witnessed CCS representatives providing kickbacks such as free lunches to doctors to push the sale of pumps. CCS representatives have a quota of pumps they have to sell on a monthly basis. To make sure they meet their quotas, CCS representatives provide free lunches in cooperation with Medtronic representatives and CCS representatives provide classes on diabetes where the main goal is to get Medicare and Medicaid beneficiaries to purchase an insulin pump and supplies from CCS. One CCS employee that has knowledge of these activities is Stacy Curzon.

59. Defendant Minimed Distribution Corp. also has provided free wine and televisions to physicians and their practices. An example of a physician that has received such free items includes Karen Port, M.D.

60. Defendants' acts and omissions, as set forth above, violate federal law and claims submitted to any government-funded health care program that were the result of such acts and omissions constitute false or fraudulent claims for reimbursement.

CLAIMS

Count I

Violation of the False Claims Act

31 U.S.C. § 3729

61. Relators reallege and incorporate by reference all of the allegations set forth above.

62. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, *et seq.*, as amended.

63. Defendants have intentionally and knowingly caused to be presented false or fraudulent claims for payment or approval by the government in violation of 31 U.S.C. § 3729(a)(1)(A) when they (1) directly solicited federal health care beneficiaries in violation of federal law, (2) certified to the medical necessity of replacement pumps when such replacement was not reasonable and necessary, (3) failed to honor warranties on Medtronic's insulin pumps in violation of federal law, (4) provided free services to physicians which were billed to Medicare and Medicaid by the physicians, and (5) provided kickbacks to physicians to encourage prescriptions and provided kickbacks to patients to encourage them to elect to replace their pumps. Each of the claims listed in paragraph 45 above is an example of a false claim that has resulted from these activities.

64. Defendants have intentionally and knowingly made, used or caused to be made false records or statements material to false or fraudulent claims for payment or approval by the government in violation of 31 U.S.C. § 3729(a)(1)(B).

65. Defendants have, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, conspired to defraud the United States government by intentionally and knowingly causing false or fraudulent claims to be paid or approved by the government in violation of 31 U.S.C. § 3729(a)(1)(C). Medtronic's distributors, including CCS and Minimed, know that Medtronic is directly soliciting Medicare and Medicaid beneficiaries and sending the leads generated from this direct solicitation to CCS or Minimed which then contact the beneficiaries in violation of 42 U.S.C. § 1395m(a)(17)(A) and 42 C.F.R. § 424.57(c)(11) to sell Medtronic's pumps. As set forth above, Medtronic's sales representatives work closely with CCS representatives to make sure that all Medicare beneficiaries are directly solicited for a new or replacement pump. Medtronic and CCS's sales representatives conduct weekly "pipeline reviews" for these purposes. In fact, Medtronic has access to what is called the "CCS Tracker" which tells Medtronic the status of its pump sales to Medicare beneficiaries. Medtronic has a similar arrangement with Minimed. Each of the claims listed in paragraph 45 above is an example of a false claim that has resulted from these conspiracies.

66. Additionally, Relators assert a claim under the False Claims Act for Defendants' numerous violations of the Anti-Kickback Statute, 42 U.S.C. § 1395m(a)(17)(A) and 42 C.F.R. § 424.57(c)(11) and their false certifications of compliance with such statutes. Such certifications are a condition to receiving government benefits.

67. The United States, its fiscal intermediaries and State Medicaid programs, were unaware of Defendants' conspiracies or the falsity of the records, statements and claims made or

caused by Defendants and as a result have paid and continue to pay Defendants for pumps that were sold as a result of illegal direct solicitation, that are not medically necessary, and that were sold as a result of free services or kickbacks by Defendants to prescribing physicians.

68. The United States and the state Medicaid programs have been damaged by the payment of false or fraudulent claims.

Count II

Violation of the Arkansas False Claims Act

Ark. Code Ann. § 20-77-901, *et seq.*

69. Relators reallege and incorporate by reference all of the allegations set forth above.

70. This is a claim for treble damages and penalties under the Arkansas False Claims Act.

71. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Arkansas State Government for payment or approval.

72. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Arkansas State Government to approve and pay such false and fraudulent claims.

73. The Arkansas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal acts.

74. By reason of the Defendants' acts, the State of Arkansas has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

75. The State of Arkansas is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants, plus three times the amount of all payments judicially found to have been fraudulently received from the Arkansas Medicaid program.

Count III

Violation of the California False Claims Act

CAL. GOV'T CODE §12651

76. Relators reallege and incorporate by reference all of the allegations set forth above.

77. This is a claim for treble damages and penalties under the California False Claims Act.

78. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

79. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims.

80. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal acts.

81. By reason of the Defendants' acts, the State of California has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

82. The State of California is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count IV

Violation of the Colorado Medicaid False Claims Act

Colo. Rev. Stat. § 25.5-4-303.5, *et seq.*

83. Relators reallege and incorporate by reference all of the allegations set forth above.

84. This is a claim for treble damages and penalties under the Colorado Medicaid False Claims Act.

85. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Colorado State Government for payment or approval.

86. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Colorado State Government to approve and pay such false and fraudulent claims.

87. The Colorado State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal acts.

88. By reason of the Defendants' acts, the State of Colorado has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

89. The State of Colorado is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants, plus three times the amount of damages that the state sustained.

Count V

Violation of the Connecticut False Claims Act

Conn. Gen. Stat. § 17b-301, *et seq.*

90. Relators reallege and incorporate by reference all of the allegations set forth above.

91. This is a claim for treble damages and penalties under the Connecticut False Claims Act.

92. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Connecticut State Government for payment or approval.

93. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Connecticut State Government to approve and pay such false and fraudulent claims.

94. The Connecticut State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal acts.

95. By reason of the Defendants' acts, the State of Connecticut has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

96. The State of Connecticut is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants, the costs of investigation and prosecution of such violations, plus three times the amount of damages that the state sustained.

Count VI

Violation of the Delaware False Claims and Reporting Act

DEL. CODE ANN. tit. 6, §1201

97. Relators reallege and incorporate by reference all of the allegations set forth above.

98. This is a claim for treble damages and penalties under the Delaware False Claims and Reporting Act.

99. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

100. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

101. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal acts as described above.

102. By reason of the Defendants' acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

103. The State of Delaware is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count VII

Violation of the District of Columbia False Claims Act

D.C. CODE § 2-308.14

104. Relators reallege and incorporate by reference all of the allegations set forth above.

105. This is a claim for treble damages and penalties under the District of Columbia False Claims Act.

106. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia for payment or approval.

107. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia to approve and pay such false and fraudulent claims.

108. The District of Columbia, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal acts.

109. By reason of the Defendants' acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

110. The District of Columbia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count VIII

Violation of the Florida False Claims Act

FLA. STAT. § 68.082

111. Relators reallege and incorporate by reference all of the allegations set forth above.

112. This is a claim for treble damages and penalties under the Florida False Claims Act.

113. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

114. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

115. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal practices.

116. By reason of the Defendants' acts, the State of Florida has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

117. The State of Florida is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count IX

Violation of Georgia False Medicaid Claims Act

GA. CODE ANN. § 49-4-168, et seq.

118. Relators reallege and incorporate by reference all of the allegations set forth above.

119. This is a claim for treble damages and penalties under the Georgia False Medicaid Claims Act.

120. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or approval.

121. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Georgia State Government to approve and pay such false and fraudulent claims.

122. The Georgia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal practices.

123. By reason of the Defendants' acts, the State of Georgia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

124. The State of Georgia is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count X

Violation of Hawaii False Claims Act

HAW. REV. STAT. § 661-21

125. Relators reallege and incorporate by reference all of the allegations set forth above.

126. This is a claim for treble damages and penalties under the Hawaii False Claims Act.

127. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

128. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims.

129. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendants' illegal practices.

130. By reason of the Defendants' acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

131. The State of Hawaii is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count XI

Violation of Illinois Whistleblower Reward and Protection Act

740 ILL. COMP. STAT. 175/3

132. Relators reallege and incorporate by reference all of the allegations set forth above.

133. This is a claim for treble damages and penalties under the Illinois Whistleblower Reward and Protection Act.

134. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

135. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

136. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal practices.

137. By reason of the Defendants' acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

138. The State of Illinois is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count XII

Violation of Indiana False Claims and Whistleblower Protection Act

IND. CODE § 5-11-5.5-2

139. Relators reallege and incorporate by reference all of the allegations set forth above.

140. This is a claim for treble damages and penalties under the Indiana False Claims and Whistleblower Protection Act.

141. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or approval.

142. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Indiana State Government to approve and pay such false and fraudulent claims.

143. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal practices.

144. By reason of the Defendants' acts, the State of Indiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

145. The State of Indiana is entitled to at least $5,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count XIII

Violation of Louisiana Medical Assistance Programs Integrity Law

LA. REV. STAT. § 437.1, et seq.

146. Relators reallege and incorporate by reference all of the allegations set forth above.

147. This is a claim for treble damages and penalties under the Louisiana Medical Assistance Programs Integrity Law.

148. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Louisiana State Government for payment or approval.

149. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Louisiana State Government to approve and pay such false and fraudulent claims.

150. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal practices.

151. By reason of the Defendants' acts, the State of Louisiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

152. The State of Louisiana is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count XIV

Violation of Maryland False Health Claims Act of 2010

Senate Bill 279, MD. CODE ANN., HEALTH-GENERAL § 2-601, et seq.

153. Relators reallege and incorporates by reference all of the allegations set forth above.

154. This is a claim for treble damages and penalties under the Maryland False Health Claims Act of 2010.

155. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Maryland State Government for payment or approval.

156. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Maryland State Government to approve and pay such false and fraudulent claims.

157. The Maryland State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal practices.

158. By reason of the Defendants' acts, the State of Maryland has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

159. The State of Maryland is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count XV

Violation of Massachusetts False Claims Law

MASS. GEN. LAWS ch. 12, § 5B

160. Relators reallege and incorporate by reference all of the allegations set forth above.

161. This is a claim for treble damages and penalties under the Massachusetts False Claims Law.

162. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Massachusetts State Government for payment or approval.

163. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Massachusetts State Government to approve and pay such false and fraudulent claims.

164. The Massachusetts State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendants' illegal practices.

165. By reason of the Defendants' acts, the State of Massachusetts has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

166. The State of Massachusetts is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count XVI

Violation of Michigan Medicaid False Claim Act

MICH. COMP. LAWS § 400.601, et seq.

167. Relators reallege and incorporate by reference all of the allegations set forth above.

168. This is a claim for treble damages and penalties under the Michigan Medicaid False Claim Act.

169. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Michigan State Government for payment or approval.

170. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Michigan State Government to approve and pay such false and fraudulent claims.

171. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

172. By reason of the Defendants' acts, the State of Michigan has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

Count XVII

Violation of Minnesota False Claims Act

MINN. STAT. § 15C.01, et seq.

173. Relators reallege and incorporates by reference all of the allegations set forth above.

174. This is a claim for treble damages and penalties under the Minnesota False Claims Act.

175. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Minnesota State Government for payment or approval.

176. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Minnesota State Government to approve and pay such false and fraudulent claims.

177. The Minnesota State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal practices and illegal inducements.

178. By reason of the Defendants' acts, the State of Minnesota has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

179. The State of Minnesota is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count XVIII

Violation of the Missouri False Claims Act

MO. Ann. Stat. § 191.900, *et seq.*

180. Relators reallege and incorporate by reference all of the allegations set forth above.

181. This is a claim for treble damages and penalties under the Missouri False Claims Act.

182. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Missouri State Government for payment or approval.

183. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Missouri State Government to approve and pay such false and fraudulent claims.

184. The Missouri State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal acts.

185. By reason of the Defendants' acts, the State of Missouri has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

186. The State of Missouri is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants, plus three times the amount of damages that the state and federal government sustained.

Count XIX

Violation of Montana False Claims Act

MONT. CODE ANN. § 17-8-401, et seq.

187. Relators reallege and incorporate by reference all of the allegations set forth above.

188. This is a claim for treble damages and penalties under the Montana False Claims Act.

189. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Montana State Government for payment or approval.

190. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Montana State Government to approve and pay such false and fraudulent claims.

191. The Montana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal practices.

192. By reason of the Defendants' acts, the State of Montana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

193. The State of Montana is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count XX

Violation of Nevada False Claims Act

NEV. REV. STAT. § 357.040

194. Relators reallege and incorporate by reference all of the allegations set forth above.

195. This is a claim for treble damages and penalties under the Nevada False Claims Act.

196. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

197. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

198. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal practices.

199. By reason of the Defendants' acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

200. The State of Nevada is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count XXI

Violation of New Hampshire False Claims Act

N.H. REV. STAT. § 167:61-b.

201. Relators reallege and incorporate by reference all of the allegations set forth above.

202. This is a claim for treble damages and penalties under the New Hampshire False Claims Act.

203. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Hampshire State Government for payment or approval.

204. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Hampshire State Government to approve and pay such false and fraudulent claims.

205. The New Hampshire State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendants' illegal practices.

206. By reason of the Defendants' acts, the State of New Hampshire has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

207. The State of New Hampshire is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count XXII

Violation of New Jersey False Claims Act

N.J. STAT. ANN. § 2A:32C-3

208. Relators reallege and incorporate by reference all of the allegations set forth above.

209. This is a claim for treble damages and penalties under the New Jersey False Claims Act.

210. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Jersey State Government for payment or approval.

211. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Jersey State Government to approve and pay such false and fraudulent claims.

212. The New Jersey State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal off-label marketing practices and illegal inducements.

213. By reason of the Defendants' acts, the State of New Jersey has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

214. The State of New Jersey is entitled to a penalty of $10,000 for the first violation and $20,000 for subsequent false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count XXIII

Violation of New Mexico Medicaid False Claims Act

N.M. STAT. § 44-9-3

215. Relators reallege and incorporate by reference all of the allegations set forth above.

216. This is a claim for treble damages and penalties under the New Mexico Medicaid False Claims Act.

217. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Mexico State Government for payment or approval.

218. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Mexico State Government to approve and pay such false and fraudulent claims.

219. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal practices.

220. By reason of the Defendants' acts, the State of New Mexico has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

221. The State of New Mexico is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count XXIV

Violation of New York False Claims Act

N.Y. STATE FIN. LAW § 189

222. Relators reallege and incorporate by reference all of the allegations set forth above.

223. This is a claim for treble damages and penalties under the New York False Claims Act.

224. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the New York State Government for payment or approval.

225. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York State Government to approve and pay such false and fraudulent claims.

226. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal practices.

227. By reason of the Defendants' acts, the State of New York has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

228. The State of New York is entitled to the maximum penalty of $12,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count XXV

Violation of North Carolina False Claims Act

N.C. GEN. STAT. § 1-605, et seq.

229. Relators reallege and incorporate by reference all of the allegations set forth above.

230. This is a claim for treble damages and penalties under the North Carolina False Claims Act.

231. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the North Carolina State Government for payment or approval.

232. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the North Carolina State Government to approve and pay such false and fraudulent claims.

233. The North Carolina State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal practices.

234. By reason of the Defendants' acts, the State of North Carolina has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

235. The State of North Carolina is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count XXVI

Violation of Oklahoma Medicaid False Claims Act

OKLA. STAT. tit. 63, § 5053, et seq.

236. Relators reallege and incorporate by reference all of the allegations set forth above.

237. This is a claim for treble damages and penalties under the Oklahoma Medicaid False Claims Act.

238. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Oklahoma State Government for payment or approval.

239. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Oklahoma State Government to approve and pay such false and fraudulent claims.

240. The Oklahoma State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal practices.

241. By reason of the Defendants' acts, the State of Oklahoma has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

242. The State of Oklahoma is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count XXVII

Violation of Rhode Island State False Claims Act

R.I. GEN. LAWS § 9-1.1-1, et seq.

243. Relators reallege and incorporate by reference all of the allegations set forth above.

244. This is a claim for treble damages and penalties under the Rhode Island State False Claims Act.

245. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Rhode Island State Government for payment or approval.

246. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Rhode Island State Government to approve and pay such false and fraudulent claims.

247. The Rhode Island State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal practices.

248. By reason of the Defendants' acts, the State of Rhode Island has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

249. The State of Rhode Island is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count XXVIII

Violation of Tennessee Medicaid False Claims Act

TENN. CODE ANN. § 71-5-182

250. Relators reallege and incorporate by reference all of the allegations set forth above.

251. This is a claim for treble damages and penalties under the Tennessee Medicaid False Claims Act.

252. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

253. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

254. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal practices.

255. By reason of the Defendants' acts, the State of Tennessee has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

256. The State of Tennessee is entitled to the maximum penalty of $25,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count XXIX

Violation of Texas Medicaid Fraud Prevention Law

TEX. HUM. RES. CODE § 36.001, et seq.

257. Relators reallege and incorporate by reference all of the allegations set forth above.

258. This is a claim for treble damages and penalties under the Texas Medicaid Fraud Prevention Law.

259. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.

260. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

261. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal practices.

262. By reason of the Defendants' acts, the State of Texas has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

263. The State of Texas is entitled to a penalty of at least $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count XXX

Violation of Virginia Fraud Against Taxpayers Act

VA. CODE ANN. § 8.01-216.3

264. Relators reallege and incorporate by reference all of the allegations set forth above.

265. This is a claim for treble damages and penalties under the Virginia Fraud Against Taxpayers Act.

266. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Virginia State Government for payment or approval.

267. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Virginia State Government to approve and pay such false and fraudulent claims.

268. The Virginia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal practices.

269. By reason of the Defendants' acts, the State of Virginia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

270. The State of Virginia is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count XXXI

Violation of Wisconsin False Claims Act

WIS. STAT. § 20.931

271. Relators reallege and incorporate by reference all of the allegations set forth above.

272. This is a claim for treble damages and penalties under the Wisconsin False Claims Act.

273. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Wisconsin State Government for payment or approval.

274. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Wisconsin State Government to approve and pay such false and fraudulent claims.

275. The Wisconsin State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal practices.

276. By reason of the Defendants' acts, the State of Wisconsin has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

277. The State of Wisconsin is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

PRAYER

WHEREFORE, Relators request a judgment against the Defendants as follows:

1. That Defendants cease and desist from violating 31 U.S.C. § 3729 *et seq.*, and the counterpart provisions of the state statutes set forth above;

2. That this court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $11,000 (as adjusted for inflation under the Federal Civil Penalties Inflation Adjustment Act of 1990) for each violation of 31 U.S.C. § 3729;

3. That Relators be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d);

4. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Arkansas has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Ark. Code Ann. § 20-77-901, *et seq.*;

5. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of California has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of CAL. GOV'T CODE § 12651;

6. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Colorado has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Colo. Rev. Stat. § 25.5-4-303.5, *et seq.*;

7. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Connecticut has sustained because of Defendants' actions, the costs of investigation and prosecution of such violations, plus a civil penalty of $10,000 for each violation of Conn. Gen. Stat. § 17b-301, *et seq.*;

8. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Delaware has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of DEL. CODE ANN. tit. 6, § 1201;

9. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the District of Columbia has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of D.C. CODE § 2-308.14;

10. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Florida has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of FLA. STAT. § 68.082;

11. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Georgia has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of GA. CODE ANN. § 59-4-168, *et seq.*;

12. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Hawaii has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of HAW. REV. STAT. § 661-21;

13. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Illinois has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of 740 ILL. COMP. STAT. 175/3;

14. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Indiana has sustained because of Defendants' actions, plus a civil penalty of at least $5,000 for each violation of IND. CODE § 5-11-5.5-2;

15. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Louisiana has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of LA. REV. STAT. § 437.1, *et seq.*;

16. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Maryland has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Maryland's Senate Bill 279, M.D. CODE ANN., HEALTH-GENERAL § 2601, *et seq.*;

17. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Massachusetts has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of MASS. GEN. LAWS ch. 12, § 5B;

18. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Michigan has sustained because of Defendants' actions, plus a civil penalty for the violation of MICH. COMP. LAWS § 400.601, *et seq.*;

19. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Minnesota has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of MINN. STAT. §15C.01, *et seq.*;

20. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Missouri has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of MO. Ann. Stat. § 191.900, *et seq.*

21. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Montana has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of MONT. CODE ANN. § 17-8-401, *et seq.*;

22. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Nevada has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of NEV. REV. STAT. § 357.040;

23. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Hampshire has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of N.H. REV. STAT. § 167:61-b;

24. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Jersey has sustained because of Defendants' actions, plus a civil penalty of $10,000 for the first violation and $20,000 for subsequent violations of N.J. STAT. ANN. §2A:32B-3;

25. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Mexico has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of N.M. STAT. § 44-9-3;

26. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New York has sustained because of Defendants' actions, plus a civil penalty of $12,000 for each violation of N.Y. STATE FIN. LAW § 189;

27. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of North Carolina has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of N.C. GEN. STAT. § 1-605, *et seq.*;

28. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Oklahoma has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of OKLA. STAT. tit. 63, § 5053, *et seq.*;

29. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Rhode Island has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of R.I. GEN. LAWS § 9-1.1-1, *et seq.*;

30. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Tennessee has sustained because of Defendants' actions, plus a civil penalty of $25,000 for each violation of TENN. CODE ANN. § 71-5-182;

31. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Texas has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of TEX. HUM. RES. CODE § 36.001, *et seq.*;

32. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Virginia has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of VA. CODE ANN. § 8.01-216.3;

33. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Wisconsin has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of WIS. STAT. § 20.931;

34. That Relators, as *Qui Tam* Plaintiffs, be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act, any applicable laws of any of the States, and/or any other applicable provisions of the law;

35. That Relators be awarded all costs and expenses of this action, pursuant to both federal and state law, including attorneys' fees and court costs in the prosecution of this suit;

36. That Relators have such other and further relief as permitted by any State's False Claims Act, or similar law; and

37. That Relators have such other and further relief that this Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relators hereby demand a trial by jury.

Respectfully submitted,

LOOPER REED & McGRAW, P.C.

By: _____

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ATTORNEYS FOR RELATORS

CERTIFICATE OF SERVICE

The undersigned hereby certifies that he has or will serve a copy of the above Complaint on the United States of America and the States in accordance with the Federal Rules of Civil Procedure.

_____
ANDREW K. YORK